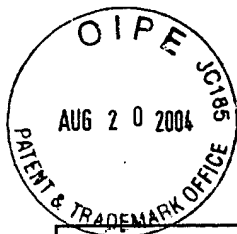


8-23-04

1642



Patent Docket P1829R1

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of  Robert D. Mass  Serial No.: 09/863,101  Filed: May 18, 2001	Group Art Unit: 1642  Examiner: Misook Yu  Confirmation No: 9233  CUSTOMER NO: 09157
For: GENE DETECTION ASSAY FOR IMPROVING THE LIKELIHOOD OF AN EFFECTIVE RESPONSE TO AN ERBB ANTAGONIST CANCER THERAPY	Express Mail No. EV 351 924 878 US  <u>August 20 2004</u> <u>Wm Lee</u> Wendy M. Lee

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

**(X) 37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

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**37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set

forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in 37 CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

(If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.)

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) and/or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (\*) in the attached PTO-1449 form are not supplied because **a)** ☐ they were previously cited by or submitted to the Office in a prior application Serial No. , filed and relied upon in this application for an earlier filing date under 35 USC §120 **and/ or** because **b)** ☐ this application was filed after June 30, 2003. Applicants are no longer required to submit copies of U.S. patents and U.S. patent application publications cited in information disclosure statements for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC §371 after June 30, 2003 (**1276 OG 55**). Nevertheless, applicants stand ready to provide copies at the request

of the Examiner.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1 - A-0" (nucleotide) and "BLAST Results B-1 - B-0" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☒ given for only non-English language listed item(s) (Required)  
An English language abstract appears on the cover of reference number 339.

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: August 20, 2004

By: WML  
Wendy M. Lee  
Reg. No. 40,378  
Telephone No. (650) 225-1994

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark OfficeAtty Docket No.  
P1829R1Serial No.  
09/863,101

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Mass, Robert D.

Filing Date

18 May 2001

Group

1642

## U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
	320	2002/0064785	30.05.02	Mass, R.		
	321	2002/0090662	11.07.02	Ralph, P.		
	322	2002/0141993	03.10.02	Ashkenazi et al.		
	323	2002/0142328	03.10.02	Danenberg, K.		
	324	2002/0192211	19.12.02	Hudziak et al.		
	325	2003/0059790	27.03.03	Jaffee et al.		
	326	2003/0108545	12.06.03	Rockwell et al.		
	327	2003/0134344	17.07.03	Mass, R.		
	328	2003/0144252	31.07.03	Furr, B.		
	329	2003/0152987	14.08.03	Cohen et al.		
	330	2003/0157097	21.08.03	Noguchi et al.		
	331	2003/0170234A1	11.09.03	Hellmann		
	332	2003/0211530	13.11.03	Danenberg, K.		
	333	2004/0037823	26.02.04	Paton et al.		
	334	6,387,371 B1	14.05.02	Hudziak et al		
	335	6,399,063 B1	04.06.02	Hudziak et al		
	336	6,407,213	18.06.02	Carter et al.		
	337	6,573,043	03.06.03	Cohen et al.		
	338	6,602,670	05.08.03	Danenberg, K.		
	339	6,627,196	30.09.03	Baughman et al.		
	340	6,632,979	14.10.03	Erickson et al.		
	341	6,719,971	13.04.04	Carter et al.		

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes No
	342	WO 01/76630	18.10.01	PCT (ENGLISH ABSTRACT ON COVER)		
	343	WO 01/89566	29.11.01	PCT		
	344	WO 02/055106	18.07.02	PCT		
	345	WO 02/45653	13.06.02	PCT		
	346	WO 99/48527	30.09.99	PCT		

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

347	Cobleigh et al., "Multinational study of the efficacy and safety of humanized anti-HER2 monoclonal antibody in women who have HER2-overexpressing metastatic breast cancer that has progressed after chemotherapy for metastatic disease" <u>Journal of Clinical Oncology</u> 17(9):2639-2648 (Sep 1999)
348	Slamon et al., "Use of chemotherapy plus a monoclonal antibody against HER2 for metastatic breast cancer that overexpresses HER2" <u>New England J. of Medicine</u> 344(11):783-792 (Mar 15, 2001)
349	Statement Regarding HERCEPTIN Clinical Trials pps. 1 (2004)

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.